



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/252,486 02/18/99 MESENS J 00166.0051US

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EXAMINER

SACKEY, E

ART UNIT

PAPER NUMBER

1613

DATE MAILED:

01/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/252,486

Applicant(s)

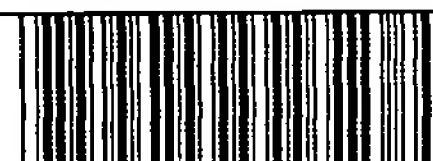
JEAN MESENS ET AL.

Examiner

EBENEZER SACKY

Group Art Unit

1613



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-11, 28, and 29 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11, 28, and 29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the signature of the first named inventor is missing.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-11, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen et al. (U.S. Patent No. 5,158,952).

Jansen et al. disclose 3-[2-[4(6-fluoro -1, 2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-9-hydroxy-2-methyl-4H-pyrido[1,2-A]pyrimidin-4-one

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compound, (also known as 9-hydroxy-risperidone), a method of using the said compound and derivatives thereof in the treatment of psychotic disorders in warm blooded animals. See column 13, lines 3-10, 24-26 and 33-44.

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-11, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen et al. (U.S. Patent No. 5,158,952) and Megens et al. "In vivo pharmacological profile of 9-hydroxyrispridone---", Preclinical Research Report R 64 766/R76 477, 26 pages, (May 1993) in combination.

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Applicants claim a method of using a composition comprising 1,2-benzazole as depicted in claim 1 formula to treat warm-blooded animals suffering from psychotic disorders.

Jansen et al. teach an identical compound used as an antipsychotic agent. See column 12, lines 44-48. The difference between the instant invention and Jansen et al. is in the generic description of the composition used in treating warm-blooded animals. Megens et al teach a composition comprising risperidone, which is analogous to 9-hydroxy risperidone. However, Megens teach that the two compositions have comparable effects in similar dosages. Furthermore, 9-hydroxy risperidone is the major metabolite of risperidone.

One of ordinary skill in the art would thus have been motivated to combine the teachings of Jansen et al. and Megens et al. to arrive at the instant invention because Megens teach that the pharmacological properties of risperidone is similar to 9-hydroxy-risperidone and therefore, formulations containing 9-hydroxy-risperidone would possess similar properties on warm blooded animals suffering from psychotic disorders. Further, risperidone is

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known to have antipsychotic properties, risperidone would be expected to be metabolized to 9-hydroxy-risperidone and structurally similar compounds and compositions are expected to exhibit similar properties. The instantly claimed compound and method of use would have been suggested to one of ordinary skill.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4532. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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January 15, 2000

Joseph K. McKane

Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1613, Group 1600

Technology Center 1